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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/779,095	02/08/2001	Jean-Louis Gueret	20982-13	1674

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/779,095	GUERET, JEAN-LOUIS	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-30 and 35-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-30 and 35-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicant's Appeal Brief filed 05/21/2008.

The finality of the Office action mailed 06/22/2007 is hereby withdrawn.

Claims 2-4, 31-34 have been canceled.

Claims 1, 5-30, 35-65 are pending and included in the prosecution.

The following rejections were discussed in details in the previous office action, and are maintained for reasons of record:

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 66-68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

had possession of the claimed invention. Claims 66-68 that were added by the amendment filed 03/26/2007 had introduced new matter as the claims recite the limitation "substantially constant thickness". Recourse to the specification does not disclose anywhere that the composite has substantially constant thickness. In paragraph 0022 of the published application, applicant disclosed that: "These two support layers can be of different roughnesses, porosities, or thicknesses so as to make two different types of application possible depending on which face is selected by the user." In paragraph 0062 applicant disclosed: "The support layers 12 and 13 can be of different thicknesses." In paragraph 0077 applicant disclosed: "The composite structure 40 of the embodiment shown in FIG. 4 comprises an adhesive matrix 41 sandwiched between two support layers 42 and 43 respectively constituted by a polyethylene film having a thickness of 40 micrometers (.mu.m) and by a hydrophilic non-woven cloth with a weight per surface area of 40 g/m.sup.2, made up of a mixture of polypropylene and viscose fibers". In paragraph 0085 applicant disclosed: "FIG. 7 shows a composite structure 70 comprising an adhesive matrix 71 sandwiched between support layers 72 and 73 of different thickness". Therefore, no disclosure whatsoever in the specification for "composite that has substantially constant thickness". In accordance to MPEP 714.02, applicant should specifically point out to where in the disclosure a support for any amendment made to the claims can be found.

Response to Arguments

3. Applicant's arguments filed 05/21/2008 have been fully considered but they are not persuasive. Applicant relies on figures 1-11 and 14-16 for support of the limitation of "constant thickness" and argues that the figures show composite structure having substantially constant thickness.

In response to this argument, it is argued that figures 1-11 and 14-16 are only representation of the disclosed device and not the actual figures of the device. Additionally, the figures do not show any thickness and the "Description of the Drawing" does not describe thickness of the device. Therefore, the figures did not contemplate that the disclosed device has constant thickness.

4. Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection. Claim 9 is directed to moisture absorbing compounds including "freeze-dried substances". The specification gives no guidance to one of ordinary skill in the art regarding "freeze-dried substances" that fulfill the requirement as moisture absorbing compounds. The disclosure of the broad expression "freeze-dried substances" without partial or complete description of any freeze-dried substances does not convey to one of ordinary skill in the art that applicants were in possession of the claimed subject matter that encompass all

substances. The recitation of "freeze-dried substances" without any description of these substances and their correlation to the moisture absorbing compounds does not meet the written description requirement as one of ordinary skill in the art could not recognize or understand the what are the freeze dried materials that acts as moisture absorbing compounds. Claims employing broad terms at the point of novelty, such as applicants', neither provide those elements required to practice the inventions, nor "inform the public" during the life of the patent of the limits of the monopoly asserted. The expression could encompass myriad of freeze-dried substances and applicants claimed "freeze-dried substances" represents only an invitation to experiment regarding possible means.

To satisfy the Written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that applicant were in possession of the claimed invention. Vas-Cathy Inc. v Mahurkar, 19 USPQ 2d 1111. The invention is, for purpose of the "written description" inquiry, what ever is now claimed.

Response to Arguments

5. Applicant's arguments filed 05/21/2008 have been fully considered but they are not persuasive. Applicant argues that there is no reasonable basis to challenge the adequacy of written description of the term "freeze dried substances" in the context of moisture absorbing compounds, and the Examiner has not demonstrated by a

preponderance of evidence why person skilled in the art would not recognize the description of the invention defined by the claims.

In response to this argument, it is pointed out to the scope of claim 9 that encompasses all substances that can be freeze dried, because the claim reads as " the moisture absorbing substance includes freeze dried substances". Nowhere in the specification applicant has disclosed freeze-dried substances that are suitable as moisture absorbing agents. Are these substances one of those moisture-absorbing substances listed in the claims, or other substances? One skilled in the art would not recognize the freeze-dried substances that can be used in the present invention as defined by the claims. Applicants are not in possession to, as of the filing date of the claims, "freeze dried substances" and not informing the public during the life of the patent of the limits of the monopoly asserted. Applicant failed to provide the necessary information regarding "substances" that can be freeze dried and used in the present invention.

The following are the new grounds of rejections:

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A broad range or limitation together with a narrow range or

limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. The claims are rendered indefinite by raising a question or doubt introduced by the broad and narrow limitations because it is subject of more than one interpretation, and one interpretation would render the claim unpatentable over the prior art. In the present instance, the broad limitation is "vinyl" and the narrow limitations are "PVP and PVA".

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 5-11, 14-18, 27, 36-44, 47-52, 54-57, 59, 60, 65-68 are rejected under 35 U.S.C. 102(b) as being anticipated by CA 2186042 ('042).

The present claims 1, 54-56 are drawn to article comprising two non-adhesive layers, at least one of these layers is permeable to a solvent, and an adhesive layer disposed between the two non-adhesive layers and comprises adhesive and active agent that can be delivered upon wetting of the article. Claim 27 is directed to conventional method of making the article that comprises the steps of coating the composition comprising the adhesive on the first non-adhesive layer, and then assembling the second non-adhesive layer.

CA '042 disclosed cosmetic or skin-pharmaceuticals patch for controlled release of at least one cosmetic compound or skin pharmaceutically active on the skin. The patch comprises occlusive support layer and protective layer and polymer matrix enclosed in between the protective and the support layers. The polymer matrix consists of a hydrophobic polymer in which are scattered evenly particles of active compound and particles of at least one hydro-absorbent agent. The matrix is based on a silicone polymer or polyurethane. Such patches have structure consisting of several layers in the following order: a first layer is support layer, second layer is polymer matrix attached to the support layer containing the active compound, this layer can come directly in contact with the skin; possibly, to facilitate the fixing of the patch on the skin, a layer of a material adhesive applied to the surface of the reservoir/matrix layer and permeable to active compound; finally, a detachable layer of protection. The patch includes a perforated frame sheet of a non-woven natural or synthetic fibers and a net by natural or synthetic fibers, and support layer made of a polymer chosen from among polyethylene high and low density, polypropylene, polyvinyl chloride, ethylene copolymers and acetate vinyl, polyester and polyurethanes. The reference teaches method of making the patch that reads on the method claimed by claim 27 comprising mixing the ingredients, and spreading the mixture with a blade in a layer 0.8 mm thick on a sheet of polyethylene with a thickness of 200 mu m, applying the nylon polyethylene net and applying a film of polyethylene of 30 mu m thick layer which is the support or occlusive patch, and it proceeded to calendering of the whole., thus providing a patch with an support occlusive layer and a self-adhesive reservoir layer composed of a polymer

matrix silicone partially reticulate, and a layer of protection. (See example 1). Therefore, the polymer matrix is disclosed as being adhesive, and also disclosed as being between support layer and nylon polyethylene perforated net. (See claims 14-16, page 4 of the translation). The reference disclosed in the second full paragraph of page 6 that the polymer layer containing the drug can be self adhesive. (See page 3, claims 1-3 of the provided translation, and page 4). The active compounds are chosen from vitamin C, vitamin A, vitamin E, enzymes and antibiotics, and the hydro-absorbing agent is chosen from polyacrylates superabsorbent, polyvinyl alcohol, carboxyvinyl polymers, semi-synthetic derivative of cellulose, starches, guar gum, Arabian or adragante, casein, phytocolloides, cotton fibre and gelatin, all meet the limitation of claims 7 and 9. The hydro-absorbent particles are in the form of a freeze-dried powder possibly containing at least one active substance. The matrix further comprises powdered soy protein and wheat which read on polyamide powder claimed by claims 43 and 44 (See claims 8-11, page 3 and page 6 of the translation). In contact with moisture from the skin (or possibly in the presence of water applied to the skin or shell layer) particles of hydro-absorbent react and then gradually release the particles of active compound, i.e. the active agent is released from the patch when the patch is wetted with water and contacted the skin as required by the generic claims, and claims 5, 6, 47-49, 65. (See page 5 of the translation). The reference teaches that the cosmetic compound or skin pharmaceutically asset is present in a proportion of between about 0.2 and 48% by weight and hydro-absorbing agent in a proportion of between about 0.1 and 30% by weight compared to the total weight of the matrix layer that read on the amounts

claimed in claims 8 and 42 (See page 6). The hydro-absorbing agents are expected to be capable to absorb water and form a hydrogel, and that reads on the limitations of claims 36-41. The reference disclosed middle adhesive matrix including polyurethane and silicone polymers that are expected to be able to permanently bond to the first and second layers.

10. Claims 19-26, 28-30, 35, 45, 46, 53, and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over CA '042 in view of US 5,350,581 ('581).

The combined teachings of CA '042 and US '928 are discussed in section 9 as set forth in this office action.

The teachings CA 042 suggested delivery of more than one active agent.

However, CA '042 does not teach more than one superimposed layers containing adhesive or pile of the article as claimed in claims 19-26, 28-30, 35, 45, 46, 53, and 58.

US '581 teaches multilayered transdermal therapeutic system assembled from superimposed monolithic unites to obtain the finished device (abstract). The device comprises more than one therapeutic agent contained in different adhesive matrices to deliver mixture of therapeutic agents (col.5, lines 30-55). The multilayered device has improved reliability and is produced by manipulable steps (col.2, lines 33-38). Example of drugs to be delivered by the device anti-inflammatory drugs, ant-histaminic drugs, and vasodilators (col.5, lines 58-67).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an article comprising two non-adhesive layers and a middle layer disposed in between the non-adhesive layers and comprises adhesive matrix and therapeutic agent wherein more than one active agents can be enclosed separate from one another in the article as disclosed by t CA '042, and provide the different active agent in more than one superimposed adhesive layers as disclosed by US '581, motivated by the teaching of US '581 that multilayered device has improved reliability and is produced by manipulable steps, and deliver mixture of beneficial therapeutic agents, with reasonable expectation of having article comprising two non-adhesive layers and a middle layer disposed in between the non-adhesive layers and comprises multiple layers comprises adhesive matrix and different therapeutic agent wherein more than one active agents can be delivered from improved reliable device.

11. Claims 12, 13, 61-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over CA '042 in view of JP 04108710 ('710).

The teachings of CA '042are discussed in section 9 as set forth in this office action.

However, CA '042 does not teach magnetizable particles in the therapeutic composition.

JP '710 teaches cosmetic in adhesive matrix comprising magnetizable particles that are capable of promoting of blood flow to the skin without causing inflammation to the skin (abstract).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an article comprising two non-adhesive layers and a middle layer disposed in between the non-adhesive layers and comprises adhesive matrix and therapeutic agent as disclosed by CA '042, and add magnetizable particles to the active agent containing layer as disclosed by JP '710, motivated by the teaching of JP '710 that the magnetizable particles are capable of promoting the blood flow to the skin without causing its inflammation, with reasonable expectation of having an article comprising two outer layers and middle adhesive layer comprising magnetizable particles that promotes the blood flow to the skin without causing its inflammation.

Response to Arguments

12. Applicant's arguments with respect to claims 1, 5-30, 35-65 have been considered but are moot in view of the new ground(s) of rejection.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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